DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 6, 2014

Waldemar Link GmbH and Company, KG
Thomas Mehler, Ph.D.
Director Quality Management
Barkhausenweg 10
22339 Hamburg
GERMANY

Re: K142187
Trade/Device Name: LINK® MP® Reconstruction Prosthesis
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, JDI
Dated: August 4, 2014
Received: August 8, 2014

Dear Dr. Thomas Mehler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142187 (page 1/1)

Device Name

LINK® MP® Reconstruction Prosthesis

Indications for Use *(Describe)*

The LINK® MP® Reconstruction Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The LINK® MP® Reconstruction Hip Prosthesis is indicated for the following conditions:

1) Revision arthroplasty due to juxta-articular bone defects.
2) Revision of loosened femoral prosthesis components involving extensive bone resorption of the proximal femur and widening of the medullary cavity or marked thinning of proximal femoral cortical bone.
3) Revision of loosened femoral prosthesis components by peri- / subprosthetic fracture.
4) Deformed proximal femur due to fractures or osteotomies.
5) Correction of bone deficiencies, e.g. due to tumors.
6) Large post-revision and post-trauma segmental bone defects.

The LINK® MP® Reconstruction Prosthesis is for cementless use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

N/A

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

510(k) Submitter:

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Date Prepared:

August 4th, 2014

Trade Name:

LINK® MP® Reconstruction Prosthesis

Common Name:

Hip Revision Prosthesis

Classification Name:

Prosthesis Hip, Semi-Constrained, Metal/Polymer, Uncemented; 21 CFR §888.3360, product code LWJ

Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented; 21 CFR §888.3350, product code JDI

Prosthesis, Hip, Semi-Constrained, Metal / Ceramic / Polymer, Cemented or Non-Porous, Uncemented; 21 CFR §888.3353, product code LZO

Classification and Panel:

Class II, Orthopedic / 87

Predicate Devices:

LINK® MP® Reconstruction Hip (K955296)

Device Description:

The *LINK*® MP® Reconstruction Prosthesis modular system consists of Prosthesis Heads, Stems, Neck Segments, Proximal Spacers, and Expansion Bolts. The modular components are interchangeable allowing for independent positioning. The Prosthesis Stems are available in a variety of diameters and lengths. Neck Segments are available in a variety of CCD angles and sizes. Proximal Spacers are available in a variety of heights and can be used independently or combined to add leg length. Expansion Bolts are used to secure the Neck Segments and Proximal Spacers, when used, to the modular Prosthesis Stems. Additional features include a tapered stem with a

microporous surface. The Prosthesis Stems also include longitudinal fluting.

The MP® Reconstruction Prosthesis Stems (cementless) and Neck Segments are produced of Titanium Aluminum Vanadium alloy (Ti-6Al-4V). Proximal Spacers and Expansion Bolts are made of Cobalt Chromium Molybdenum casting alloy (CoCrMo) materials.

Indications for Use:

The *LINK*® MP® Reconstruction Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The *LINK*® MP® Reconstruction Hip Prosthesis is indicated for the following conditions:

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3) Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
4) Deformed proximal femur due to fractures or osteotomies.
5) Correction of bone deficiencies, e.g. due to tumors.
6) Large post-revision and post-trauma segmental bone defects.

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Comparison to Predicate Device:

The subject device has the same intended use as the predicate and uses materials identical to those used in the predicate. The design of the subject and predicate devices has the same technological characteristics except: the subject device Neck Segments are made of Ti-6Al-4V instead of CoCrMo; additional Prosthesis Stem and Neck Segment sizes and configurations have been introduced; and a hex head Expansion Bolt is used in place of the predicates Slot Head Fixation Screw.

The performance testing is sufficient to demonstrate that the subject and predicate devices are substantially equivalent with regard to design. Any difference between the subject and predicate device does not change the intended use or fundamental scientific technology.

Performance Data:

Non-Clinical Performance and Conclusions:

Non-Clinical performance testing was conducted with consideration to *Guidance for Industry and FDA Staff, Non-Clinical Information for Femoral Stem Prosthesis, September 17, 2007 and Guidance Document For Testing Non-Articulating,"Mechanically Locked", Modular Implant Components, May 1, 1995.*

Non-clinical performance testing included: femoral stem fatigue tests per ISO 7206-4 and ISO 7206-8; femoral neck segment fatigue tests per ISO 7206-6; ASTM F2068; Modular Connections, Fretting, and Corrosion Testing per ASTM F1875-98.

The results of non-clinical performance testing demonstrated that the device is as safe, as effective, and substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

There was no clinical performance testing required for this device.